

November 13, 2006

California Blood Lead Proficiency Assurance Program (CBLPAP).

Laboratories that wish to be reimbursed for the analytical portion of blood lead testing by the State of California Department of Health Services (CDHS) Child Health and Disability Prevention Program (CHDP) must be enrolled and deemed proficient in CBLPAP and must:

- have a CLIA certificate of waiver, compliance or accreditation as appropriate to the level of testing offered by the laboratory.
- be registered or licensed with the State of California, Laboratory Field Services (LFS).
- electronically report all blood lead level results, for both adults and children, to the State of California, Childhood Lead Poisoning Prevention Branch (CLPPB).
- participate in a blood lead proficiency testing (PT) program approved by the Center for Medicare and Medicaid Services (CMS) as Clinical Laboratory Improvement Amendments (CLIA) compliant, so that CBLPAP can assess the accuracy of the testing for CLPPB and for reimbursement by the Child Health and Disability Prevention Program (CHDP).

For information about obtaining a California registration or license, go to the State of California Department of Health Services (CDHS) Laboratory Field Services (LFS) web site at www.dhs.ca.gov/lfs and select laboratory facility licensing and "Instructions for applying for a clinical laboratory registration (or license)".

All blood lead results, of whatever level, for both adults and children, must be electronically reported to the CDHS Childhood Lead Poisoning Prevention Branch (California Health and Safety Code, Section 124130). Contact CLPPB at (510) 620-5652 for instructions on electronic reporting of blood lead results.

Laboratories that perform blood lead analyses for occupational monitoring of adults must meet federal OSHA accuracy requirements, as demonstrated by successful participation in a blood lead proficiency testing (PT) program, per the OSHA lead standards. To be in compliance with federal OSHA regulations for occupational blood lead testing, a laboratory must participate in the OSHA Blood Lead Laboratories program and must appear on the current OSHA List of Laboratories Approved for Blood

Lead Analysis. The use of new, direct read-out portable instruments that are waived from PT requirements under CLIA is still subject to the specific OSHA proficiency requirements. Venous blood should always be used for monitoring adult lead exposures, except where prohibited by medical or other reasons. For a current list of approved laboratories or more information, contact the U.S. Department of Labor's OSHA Salt Lake City Technical Center, Division of Quality Control, Salt Lake City, Utah, at (801) 233-4925 or on the web at <http://www.osha.gov/SLTC/bloodlead/index.html>.

The new, direct read-out portable instruments for blood lead level testing that are waived from PT requirements under CLIA are subject to the same proficiency requirements as any other CBLPAP laboratory. To enable CBLPAP to evaluate a laboratory's performance, the laboratory must participate in a blood lead PT program approved as CLIA compliant by CMS. To be considered proficient, all laboratories enrolled in CBLPAP must be in compliance with all applicable state and federal regulations, as well as the specific requirements for CBLPAP enrollment. Some regulations, e.g. CLIA '88, vary depending on the methodology used. The following pages describe the CBLPAP proficiency requirements and proficiency scoring criteria.

For information about CBLPAP and enrollment information contact EHLB at (510) 620-2800.

CALIFORNIA DEPARTMENT OF HEALTH SERVICES

ENVIRONMENTAL HEALTH LABORATORY BRANCH

BLOOD LEAD PROFICIENCY ASSURANCE PROGRAM

Telephone (510) 620-2876 FAX: (510) 620-2825

A BRIEF DESCRIPTION OF THE PROGRAM

The Childhood Lead Poisoning Prevention Acts of 1986 and 1991 (California Health and Safety Code Sections 124125 et seq. and 105275 et seq., respectively) require the California Department of Health Services (CDHS) to designate laboratories qualified to do blood lead testing for the CDHS Childhood Lead Poisoning Prevention Branch (CLPPB) or for any blood lead testing reimbursed through the CDHS Child Health and Disability Prevention (CHDP) program. Qualification of a laboratory requires that it is in compliance with the federal Clinical Laboratory Improvement Amendments (CLIA) of 1988, that it is: a California licensed clinical laboratory; a California approved public health laboratory; or a California waived registered laboratory, or has other licensure or approval designated by CDHS Laboratory Field Services (LFS) as equivalent, and that it is judged proficient in blood lead analysis by the CDHS Environmental Health Laboratory Branch (EHLB). Laboratories located outside of the State of California should contact LFS at (510) 873-6327 for information concerning clinical laboratory licensing or approval requirements.

A laboratory's proficiency rating for blood lead testing is based on a review of its performance in one of the blood lead proficiency testing programs recognized by EHLB. Recognized programs are currently the College of American Pathologists Blood Lead Survey (CAP), the Blood Lead Proficiency Testing Regulatory 5-sample CMS-approved Program offered by the Wisconsin State Laboratory of Hygiene in cooperation with the U.S. Public Health Service Maternal and Child Health Bureau and the Centers for Disease Control and Prevention (WSLH), the State of New York Department of Health Blood Lead Proficiency Test Survey (NYS), and the American Academy of Family Physician's Proficiency Testing program (AAFP-PT). Non-waived CLIA certification requires participation in a proficiency testing (PT) program approved by the Center for Medicare and Medicaid Services (CMS) as meeting CLIA standards. To keep our program consistent with these national standards of laboratory certification, we use only CMS-approved PT programs. Laboratories using a waived test for blood lead testing must be enrolled in a CMS-approved PT program to enable CBLPAP to rate their proficiency.

EHLB evaluates each laboratory's proficiency in blood lead analysis based on its performance in only one proficiency testing program for each four-month CBLPAP Evaluation Period. A laboratory that subscribes to more than one of the recognized proficiency testing programs must inform EHLB of its choice of proficiency testing programs to be used for the proficiency evaluation in advance of the first CBLPAP Evaluation Period for which it is evaluated. A laboratory may request to change the proficiency testing program used for its proficiency evaluation at any time by notifying EHLB of its preference in writing and making whatever arrangements are necessary for EHLB to have access to that laboratory's reported analytical results from the selected proficiency test provider. Any such changes will become effective for the next CBLPAP Evaluation Period following receipt of the notification by EHLB, provided that all reporting requirements for the change have been met before the end of the current CBLPAP Evaluation Period. It is the responsibility of each laboratory to ensure that its blood lead proficiency test results are reported to EHLB by the laboratory's chosen proficiency test provider in a timely fashion.

Missing or unreported proficiency testing results may be considered unsatisfactory performance for the purpose of determining that laboratory's proficiency rating.

To maintain the integrity of the CBLPAP evaluations, EHLB reviews copies of each laboratory's proficiency test results transmitted from the proficiency test providers to EHLB. Subscribers to the CAP Blood Lead Survey must request that CAP send a copy of their Blood Lead Survey results to the State of California Blood Lead Program. This request must be made by the participating laboratory following the procedure specified in the CAP Surveys Manual. A laboratory wishing to be evaluated on their performance in the WSLH Regulatory 5-sample CMS-approved Program must notify WSLH that a copy of their blood lead results should be sent to the State of California. Participants in the NYS Proficiency Testing Program must supply EHLB with their NYS laboratory code so that we can locate their test results in the appropriate Blood Lead Proficiency Testing reports. Participants in the AAFP-PT blood lead program must request results be sent to the California Blood Lead Program as well as California Laboratory Field Services.

A list of laboratories evaluated as proficient in blood lead testing is prepared by EHLB three times a year. A summary of the criteria used to evaluate the performance of participating laboratories is enclosed with this letter. EHLB does not certify laboratories to do occupational blood lead testing. That certification is obtained through U.S. Department of Labor, Occupational Safety & Health Administration (OSHA).

Each laboratory participating in CBLPAP is notified by letter of its status when a new list of proficient laboratories is released. A new list of proficient laboratories is released after all proficiency test reports for participating laboratories for an Evaluation Period have been received by EHLB from recognized proficiency test providers and when those results have been evaluated by EHLB according to CBLPAP standards and reports of those evaluations have been generated by EHLB. A new Laboratory joining CBLPAP is notified of its status along with all other participating laboratories. This will occur after proficiency test reports representing one complete CBLPAP Evaluation Period for the applicant laboratory have been received by EHLB from a recognized proficiency test provider, after those results have been evaluated by EHLB according to CBLPAP standards, and after reports of those evaluations have been generated by EHLB and a new list of proficient laboratories is released. A laboratory must be currently designated as proficient in blood lead analysis by EHLB and must appear on the most recent list of proficient laboratories to do blood lead testing for CLPPB projects or studies or to be reimbursed through the CDHS CHDP.

Lead exposure is a condition which is reportable to the State of California. Please contact Childhood Lead Poisoning Prevention Branch (CLPPB) at (510) 620-5652 for details about electronic reporting of blood lead results.

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A SUMMARY OF THE CBLPAP PROFICIENCY CRITERIA FOR BLOOD LEAD ANALYSIS

1. A laboratory participating in the California Blood Lead Proficiency Assurance Program (CBLPAP) is considered proficient in blood lead analysis if at least 80% of its evaluated proficiency test results as reported to EHLB by the proficiency test provider are rated satisfactory by the California Department of Health Services Environmental Health Laboratory Branch (EHLB) for at least two out of the three most recent consecutive four-month Evaluation Periods.
2. A new laboratory joining the program is considered proficient if a satisfactory rating is attained on at least 80% of its proficiency test results, as reported to EHLB by the proficiency test provider and as evaluated by EHLB, either for the initial Evaluation Period or for one of the two most recent Evaluation Periods, when two have been completed. A laboratory is considered new to our program until it has completed three Evaluation Periods.
3. A participating laboratory is considered nonproficient and removed from the list of proficient laboratories if it fails to attain a satisfactory rating on at least 80% of its test results, as reported to EHLB by the proficiency test provider and as evaluated by EHLB, for two out of three consecutive Evaluation Periods.
4. A laboratory that has been rated nonproficient and removed from the list of proficient laboratories will be considered proficient and restored to the list only after it has attained a satisfactory rating on at least 80% of its test results, as reported to EHLB by the proficiency test provider and as evaluated by EHLB, for each of two consecutive Evaluation Periods.
5. An individual proficiency test sample result is judged satisfactory if the reported value is within 10% of the target value for samples with lead concentrations greater than 40 µg/dL and plus or minus 4 µg/dL for samples with lead concentrations equal to or less than 40 µg/dL.

Participating laboratories are evaluated triannually. A report of the evaluation is sent to each laboratory and an updated list of proficient laboratories is released for each four month Evaluation Period after all of the participating laboratories' results have been received by and evaluated by EHLB as summarized above and as defined in other communications to the laboratories. A laboratory must be currently designated proficient in blood lead analysis by this proficiency assurance program to do any blood lead testing for the CDHS Childhood Lead Poisoning Prevention Branch (CLPPB) or to be reimbursed through the CDHS Child Health and Disability (CHDP) program.